

GNE3230R1C34



PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Goddard et al. (as amended)  
 Appl. No. : 10/063,549  
 Filed : May 2, 2002  
 For : POLYPEPTIDES ENCODED BY  
       A NUCLEIC ACID  
       OVEREXPRESSED IN  
       ESOPHAGEAL AND KIDNEY  
       TUMOR (as amended)  
 Examiner : Patricia Ann Duffy  
 Group Art Unit : 1645

DECLARATION UNDER 37 CFR §1.131

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Dear Sir:

We declare and state as follows:

1. We are the inventors of the invention claimed in the above-captioned patent application.
2. During the time period in which we participated in the events and activities described herein, we were employed by Genentech, Inc., the assignee of the above-captioned application.
3. All of the events and activities described herein were performed by us personally, or by others at our direction as part of our duties as employees of Genentech, Inc.
4. The subject matter and utility of the claimed invention in the above-captioned patent application was conceived prior to June 11, 1998 and diligently reduced to practice thereafter in the U.S. as described below.
5. Prior to June 11, 1998, I and/or my co-inventors conceived of the invention claimed in the above-captioned patent application. Prior to June 11, 1998, the idea of investigating several newly discovered DNA sequences for their relevance, including developing primers and cloning the DNA sequences of interest from normal and tumor tissues, was conceived. The sequences of SEQ ID NOs: 45 and 46 were first disclosed in U.S. Provisional Application 60/088863, filed June 11, 1998, as SEQ ID NOs: 1 and 3, in Figures 1A-B and 2. Antibodies to said polypeptides sequence were also contemplated as disclosed in the provisional application. In addition, various utilities for the disclosed nucleic acids, polypeptides, and antibodies, including use as diagnostic

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agents, were also conceived prior to June 11, 1998, and included in the provisional application. Thus, conception of the invention claimed in the above-captioned patent application occurred prior to June 11, 1998.

6. After these initial experiments, we continued to produce primers, clone and sequence other DNA sequences. We then began to identify the expression levels of the cloned sequences, and created constructs for expression of the encoded proteins. PCR primers for use in the detection of DNA58850 expression were designed on March 6, 2000 (see Exhibit A).

7. Thereafter, the primers were used to test for expression of DNA58850 in various normal and tumor tissues. Exhibit B shows an experiment conducted in March 2000 testing for expression of DNA58850 in various normal tissues. Exhibit C shows an experiment performed on June 13, 2000, in which the primers were used to determine the expression level of DNA58850 in various tumor samples and their normal tissue counterparts. These gel data demonstrate that DNA58850 is more highly expressed in esophageal and kidney tumor than in normal esophageal and kidney tissue, respectively. These exhibits show diligence in reducing to practice following conception of the invention. Thus, we conceived of the present invention prior to June 11, 1998 and were diligent in reducing the invention to practice by at least June 13, 2000.

8. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By:   
Audrey Goddard

Date: 5/16/05

By: \_\_\_\_\_  
Paul J. Godowski

Date: \_\_\_\_\_

By: \_\_\_\_\_  
J. Christopher Grimaldi

Date: \_\_\_\_\_

By: \_\_\_\_\_  
Austin L. Gurney

Date: \_\_\_\_\_

By: \_\_\_\_\_  
William I. Wood

Date: \_\_\_\_\_

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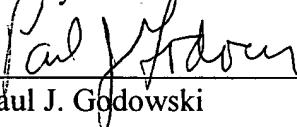
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By: \_\_\_\_\_

Audrey Goddard



Date: \_\_\_\_\_

By: \_\_\_\_\_

Paul J. Godowski

Date: 6/13/05

By: \_\_\_\_\_

J. Christopher Grimaldi

Date: \_\_\_\_\_

By: \_\_\_\_\_

Austin L. Gurney

Date: \_\_\_\_\_

By: \_\_\_\_\_

William I. Wood

Date: \_\_\_\_\_

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Audrey Goddard

Date: \_\_\_\_\_

By: \_\_\_\_\_  
Paul J. Godowski

Date: \_\_\_\_\_

By: \_\_\_\_\_  
J. Christopher Grimaldi

Date: 6/16/2005

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By: \_\_\_\_\_  
Audrey Goddard

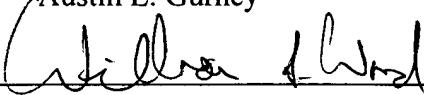
Date: \_\_\_\_\_

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J. Christopher Grimaldi

Date: \_\_\_\_\_

By: \_\_\_\_\_  
Austin L. Gurney  
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William I. Wood

Date: \_\_\_\_\_

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 Examiner : Patricia Ann Duffy  
 Group Art Unit : 1645

DECLARATION UNDER 37 C.F.R. §1.808

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Dear Sir:

I hereby aver that the nucleic acid of SEQ ID NO:45 was deposited with the American Type Culture Collection (ATCC™) August 18, 1998 and was given ATCC™ deposit number 209956. Accordingly, the deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the deposit of Microorganisms for the Purposes of Patent Procedure and all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the grant of a patent from this application.

GENENTECH, INC.

Date: 6/15/05

By: R. J. ...

Title: PATENT AGENT

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